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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,344	04/05/2001	C. Frank Bennett	RTS-0147	1718
7590 Jane Massey Licata Licata & Tyrrell, P.C. 66 East Main Street Marlton, NJ 08053			EXAMINER SCHULTZ, JAMES	
			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/828,344

Applicant(s)

BENNETT ET AL.

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 1 in part is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's responses filed July 24, and November 4, 2003 have been considered. Rejections and/or objections not reiterated from the previous office action mailed April 3, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

### ***Response to Traversal of Election/Restrictions***

Applicant's election with traverse of antisense compounds targeted to nucleobases 652 through 1064 of SEQ ID NO: 3 in the paper filed November 4, 2003 is acknowledged. The traversal is on the ground(s) that the sequences cannot be independent because they all target and modulate the same single sequence, namely SEQ ID NO:3. Applicants assert that there is a

disclosed and acknowledged relationship between the sequences. This is not found persuasive because while each sequence may be related to a target sequence, each antisense sequence is not otherwise related to any other antisense sequence. The fact that the antisense sequences encompassed by claim 1 are related to a common target does not confer upon them a common core structure that is shared between the antisense sequences. To the contrary, the antisense sequences encompassed in applicants' claim 1 are structurally and functionally independent and distinct because each antisense sequence necessarily has a unique nucleotide sequence, each targets a different and specific region of the molecule encoding human Phospholipid scramblase I, and each sequence, upon binding to the molecule encoding Phospholipid scramblase I, functionally increases or decreases the expression of the gene to varying degree as evidenced in Table 1 of the specification). Furthermore, applicants' assertion that there is no added search burden because a search of SEQ ID NO: 3 would reveal all art against that target is not considered convincing, because the search of SEQ ID NO: 3 is not intended to be an exhaustive, all-encompassing search. Such a search would potentially yield a staggering and unwieldy number of hits that are complementary and are between 8 and 50 nucleotides long. Out of necessity, the search is designed to return a manageable number of good results, such that the Office is able to cite the best art against applicants' broad claim 1 as required by 37 CFR 1.104(c), as opposed to the exhaustive list apparently envisioned by applicants. Each sequence must be searched separately as claimed, and applicant's amendment to recite distinct regions serves essentially to claim distinct sequences, since each region is a unique sequence. Accordingly, the search of multiple regions is considered to be a search burden, and is the requirement is still deemed proper and is therefore made FINAL.

The subject matter of claim 1 drawn to target regions of SEQ ID NO: 3 other than nucleobases 652 to 1064 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed November 4, 2003.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, and by dependency claims 2, 4-10, and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of claim 1 is reproduced exactly as follows: "A compound 8 to 50 nucleobases in length targeted to nucleobases 26 through 61, nucleobases 117 through 220 of a 5'-untranslated region, nucleobases 268 through 351, nucleobases 440 through 572, nucleobases 652 through 1064, or nucleobases 1180 through 1207 of a coding region, or nucleobases 1239 through 1618, nucleobases 1707 through 1908, or nucleobases 2017 through 2062 of a 3'-

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untranslated region of a nucleic acid molecule encoding Phospholipid scramblase I (SEQ ID NO: 3), wherein said compound specifically hybridizes with one of said regions and inhibits the expression of Phospholipid scramblase I”

Claim 1 recites compounds that target specific regions, wherein many of said regions are not written in the alternative (i.e. using “or” language). Thus it is not clear from the claim language if the claimed compound targets one specific region, or several such regions simultaneously. For example, claim 1 reads on a compound “targeted to nucleobases 26 through 61, nucleobases 117 through 220 of a 5'-untranslated region”. However, applicants’ specification has not described a single molecule capable of targeting both regions, and the art appears to be silent as to how to make such a molecule. Recitation of the claimed regions in the alternative would be remedial.

### *Claim Rejections - 35 USC § 102/103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under these sections made in this Office action:

A person shall be entitled to a patent unless –

102(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 2, 12, and 14 are rejected under 35 U.S.C. 102(b) and 103(a) as being anticipated and/or obvious by Veugelers et al. (WO 99/37764).

The claims of the above invention are drawn to antisense compounds 8 to 50 nucleotides in length that specifically hybridizes with and inhibits the expression of Phospholipid scramblase I of SEQ ID NO: 3.

The last primer sequence presented in table 4 on page 33 of Veugelers et al. possesses sufficient identity with residues 787 to 801 of SEQ ID NO: 3 of the instant application, and would thus specifically hybridize with applicants claimed target. Although this reference does not specifically teach the function of inhibiting applicants' instant SEQ ID NO: 3 as claimed in the present application, the above-listed compound meets all the structural limitations as set forth in the instant claims. Because the sequence is substantially identical to applicant's claimed compounds, in the absence of evidence to the contrary said compound is thus considered to possess the functional limitation of specifically hybridizing with and inhibiting the expression of applicants' instant SEQ ID NO: 3. Support for this conclusion is drawn from MPEP 2112:

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.** "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound(s) of the prior art as stated lies with the applicant, as per MPEP 2112.01:

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Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the antisense compounds of claims 1, 2, 12, and 14 of the instant application are considered anticipated and/or obvious as outlined above.

Claims 1, 2, 12, and 14 are rejected under 35 U.S.C. 102(b) and 103(a) as being anticipated and/or obvious by Nicolas et al. (U. S. Patent Number 5,830,722).

The claims are drawn to the invention as described above.

SEQ ID NO: 16 of Nicolas et al. possesses sufficient identity with residues 824-835 of SEQ ID NO: 3 of the instant application, would thus specifically hybridize with applicants claimed target, and is presumed to inhibit applicants' target for the same reasons as described above.

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***Conclusion***

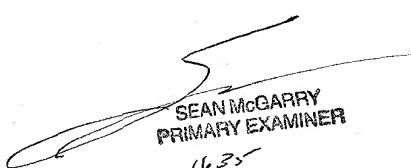
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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